

**DOCKET NO.: ALLE0016-100 DIV  
(17510 DIV1)**

**PATENT**

**REMARKS**

Upon entry of the above amendment, claims 16-21 and 36-43 will be pending in this application. The newly added claims 36-43 are fully supported by the specification. See, for example, page 19, lines 19-28, and Examples 1 and 2 at page 34. No new matter is added.

Claims 16-21 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Pat. No. 6,565,532 to Yuzhakov et al. (hereinafter "the '532 patent"). Applicants respectfully disagree, and assert that the '532 patent cannot anticipate claims 16-21, because the '532 patent does not teach all the elements in each of these claims. For example, claims 16-21 are directed to a transdermal patch comprising an *enhancing agent* that facilitates transdermal administration of the botulinum toxin. The enhancing agents of the present invention include, for example, methanol, ethanol, isopropanol, isobutanol, vesicle, transfersome and the like. See the specification at, for example, page 16, lines 13-27. Further, Examples 1 and 2 of the present specification also teach formulations comprising penetration enhancing agents that are effective to enhance the permeability of a patient's skin.

The '532 patent, on the other hand, does not teach a transdermal patch comprising an enhancing agent. The Office Action sites to the term "polymer" on column 28 of the '532 patent as teaching an enhancing agent. Office Action at page 3. The only "polymer" term on column 28 is referenced on line 63. The referenced "polymer" is not employed as an enhancing agent. In fact, the referenced "polymer" cannot be employed as an enhancing agent because it appears that the "polymer" is in the form a harden plastic/physical structure which is to be used in constructing a "close-loop system". (Other materials that may be used in constructing the "close-loop system" include diamond, metals, ceramics. See column 28, lines 62-64).

Further, instead of relying on an enhancing agent to deliver drugs, it appears that the patch in the '532 patent relies on voltage differentials to achieve the drug delivery. For example, the '532 patent discloses that

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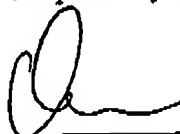
drug delivery is performed by applying an electric potential between two microneedle array electrodes. One of the electrodes is filled with an ionized drug (such as insulin), and the charged drug molecules move into the body due to the electric potential.

The '532 patent at column 28, lines 11-15.

Thus, it is clear that the '532 patent does not teach or even suggest an enhancing agent for the delivery of botulinum toxins. Accordingly, the '532 patent cannot anticipate the present claims.

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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